BEST AVAILABLE COPY

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



NED 1880 DEL SELLED FOR DEL SELLE SELLE SELLE FOR DEL CONTROL DEL CONTROL DEL CONTROL DEL CONTROL FOR DEL CONT

(43) International Publication Date 15 December 2005 (15.12.2005)

PCT

(10) International Publication Number WO 2005/117731 A1

(51) International Patent Classification⁷: 17/70

A61B 17/80,

(21) International Application Number:

PCT/GB2005/002210

(22) International Filing Date:

6 June 2005 (06.06.2005)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 0412503.5

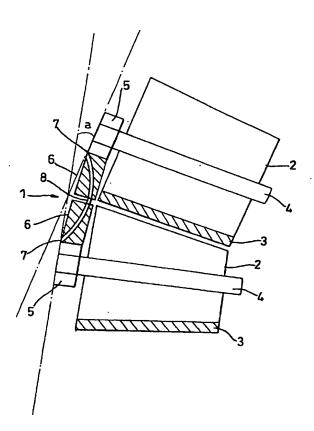
4 June 2004 (04.06.2004) GB

(71) Applicant and

- (72) Inventor: BURKE, John [IE/GB]; 55 Greenlee Drive, Little Benton, Newcastle-upon-Tyne NE7 7GA (GB).
- (74) Agent: ELSWORTH, Dominic; Hargreaves Elsworth, i6, Suite 21, 6 Charlotte Square, Newcastle-upon-Tyne NE1 4XF (GB).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD; TG).

[Continued on next page]

(54) Title: APPARATUS FOR THE CORRECTION OF SKELETAL DEFORMITIES



(57) Abstract: An implantable apparatus for use in the correction of skeletal deformities comprising a rod, a pair of spaced apart attachment members, each of the attachment members being attachable to a bone. At least one of the attachment member mounts a rod receiving member, the rod being slidable along a predetermined path with respect to the rod receiving member.

Published:

- with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

APPARATUS FOR THE CORRECTION OF SKELETAL DEFORMITIES

Field of the Invention

The invention relates to apparatus for correcting skeletal deformities, and in particular to an implantable device for controlling the relationship of bones on either side of a growth plate in paediatrics, and in adults to assist in holding bones in a locked configuration.

Background of the Invention

A number of conditions give rise to paediatric deformity, for example scoliosis (or curvature of the spine), club foot, post traumatic deformity such as cubitus varus, knock knees, etc.

Early onset scoliosis is currently managed conservatively with the use of localiser casts and braces to delay curve progression until the child is old enough for definitive treatment by instrumentation and fusion of the curve. Where conservative therapy fails, a variety of surgical procedures are used. For example, convex epiphysiodesis, stapling of the convex side of the curve, short segment fusion, and posterior growing rod systems such as the Harrigton rod, ISOLA ® growing rods or the Luque trolley system.

The Luque trolley system is described in French published patent application No 2589716 comprises a pair of U-shaped callipers fixed to the spine, one of the callipers sliding within the other so that the spine may grow. One problem with this system is that the vertebrae of the spine may fuse spontaneously as a result of exposing the spine to fit the callipers.

Using the ISOLA ® system, rods are inserted in a way that causes fusion of a small segment of spine proximally and distally to give a solid anchor for the rods. The rods do not control the sagital profile adequately and obtain their correction solely by distraction. In order to lengthen the rods to accommodate growth, the patient must be operated on every six months or so. The purpose of the pediatric ISOLA ® is to stabilize the deformity. Definitive treatment of the scoliosis usually involves

a further operation where vertebrae are fused together. Insertion of posterior growing rods and the final fusion procedure are relatively major surgical procedures especially if a thoracotomy is required for anterior release of the curve prior to insertion of the growing rods.

Factors for the development of early onset scoliosis vary considerably and include idiopathic and neuromuscular aetioligies.

Growth plates are affected by mechanical stimuli. Increased pressure on a growth plate reduces growth rate, whilst decreased pressure on a growth plate or traction can increase growth rate. Once a scoliosis curve develops the biomechanics of the spine are altered resulting in compression of the concave side of the curve and traction on the convex side of the curve. Growth on the concave side of the curve is therefore retarded whilst growth on the convex side is accelerated. The spine grows asymmetrically and the deformity is exacerbated.

In the condition known as "club foot", treatment aims are to: correct the deformity early, correct the deformity fully, and to hold the correction until growth stops. Two categories of the condition can be identified: those that are easy to correct, where correction is by splintage alone; and those that are resistant to correction, where response to splintage is poor and early operative correction is required.

Where the condition can be corrected by splintage, individual elements of foot rotation are corrected serially. In the Ponsetti method, the complex deformity is corrected by addressing each component in a defined order and only progressing to the next component when the previous has been adequately corrected. It would be useful to have a treatment which addressed all components simultaneously.

Operative correction requires the cutting of tendons and ligaments, which aside from post operative complications, tends to result in the foot being stiff in the long term.

It would therefore be desirable to develop apparatus, the use of which would improve outcomes for sufferers of conditions causing asymmetric growth.

Summary of the Invention

According to one aspect of the invention, there is provided an implantable apparatus as specified in Claim 1.

According to another aspect of the invention, there is provided an implantable apparatus according to Claim 27.

According to another aspect of the invention, there is provided a kit of parts as specified in Claim 29.

According to another aspect of the invention, there is provided a method of treating immature people as specified in Claim 30.

According to another aspect of the invention, there is provided a method of treating mature patients as specified in Claim 32.

Brief Description of the Drawings

In the drawings, which illustrate a preferred embodiment of the invention, and are by way of example:

Figure 1 is a front view of two adjacent vertebrae in a spine with a scoliosis curve having apparatus according to the invention attached thereto at the beginning of treatment;

Figure 2 is a front view of two adjacent vertebrae in a spine with a scoliosis curve having apparatus according to the invention attached thereto post treatment;

Figure 3 is front view of a spine with a scoliosis curve having apparatus according to the invention attached to vertebrae of the spine;

Figure 4a is a schematic representation of a rod for apparatus according to another aspect of the invention;

Figure 4b is an end view of a slide element designed to co-operate with the rod illustrated in Figure 4a;

Figure 5a is a schematic representation of the skeletal structure of a normal foot;

Figure 5b is a schematic representation of the skeletal structure of a club foot;

Figure 5c is a schematic representation of the lateral ray of foot bones;

Figure 5d is a schematic representation of the medial ray of foot bones;

Figure 6 illustrates the apparatus of the invention being used to correct a torsional deformity of the lower limb;

Figure 7a is a slide element comprising a first part of a locking element;

Figure 7b is a slide element comprising a second part of a locking element,

Figure 7c is an end view of a screw;

Figure 7d is a side view of the screw illustrated in Figure 7c;

Figure 7e is an end cap forming part of a locking element,

Figure 7f is an end cap forming part of a locking element;

Figure 8 is a side view of an alternative slide element;

Figure 9a is a schematic representation of another embodiment of an apparatus according to the invention in an extended configuration; and

Figure 9b is a schematic representation of the apparatus according to the invention in a retracted configuration.

Detailed Description of the Preferred Embodiments

Referring now to Figure 1, a corrective apparatus is attached to adjacent vertebrae 2 of a spine with scoliosis. Each vertebrae 2 includes a growth plate 3. A screw 4 having a head 5 is attached to each of the vertebrae 2. A bore is first drilled through the vertebrae, and then the screw is inserted into the bore. The screws 4 are hydroxyapatite coated to provide a biological fix capable of being maintained over several years. The screws have a shallow thread depth and a long pitch. The shallow thread depth allows maximum screw strength for a given screw diameter and facilitates screw removal as each screw is over-drilled prior to removal. The only difference between the screw of apparatus 1 and screws currently used for attachment to bone lies in the head 5.

The screw head 5 is provided with attachment means for attachment of a slide element 6 including an internal bore 7 in which a rod 8 slides (see Figures 7a to 7f for a more detailed description.

The rod 8 is curved, the radius of curvature being calculated to correct the angle of curvature ∂ of the spine between the adjacent vertebrae shown. It will be noted that the slide elements 6 are set at an angle to the screw heads 5. The angle is $\partial/2$. This provides the maximum room for the rod 8, and therefore permits rods having smaller radii of curvature (i.e. more aggressive correction) than if the slide elements are on axis with the screw heads 5, and the angle of curvature ∂ is taken up by the rod 8 alone. As the child grows, the adjacent vertebrae grow resulting in the distance between the screws 4 increasing. As the slide elements 6 are attached to the screw heads 5, the distance between the two slide elements increases. Due to the fixation of the slide element to the screw head 5 and the screw 4 to the vertebrae 2, the vertebrae must move in an arc corresponding to the shape of the rod 8. This arcuate movement of the vertebrae 2 not only moves the vertebrae closer to a normal position, i.e. adjacent vertebrae lying on substantially on the same axis, but also further stimulates this corrective growth by reducing pressure on the growth plate 3 remote from the slide element 6. As mentioned above, growth is more rapid where the pressure on a growth plate is reduced. As

pressure is reduced at one end of the growth plate 3, it is commensurately increased on the other side of that growth plate. The recovery to normal alignment of adjacent vertebrae is therefore enhanced.

In Figure 2, the apparatus has been in place for some time. As the child has grown, the distance between the screws 4 has increased, and only the ends of the rod 8 are located in the bores 7 in the slide elements 6. The scoliosis has been corrected.

Referring to Figure 3, a spine with a scoliosis curve is fitted with apparatus 1, as shown in Figure 1 and 2, between each adjacent vertebrae. The angle between adjacent vertebrae ranges between 0 – 5 degrees in the lower section A of the spine, 0 to 2 degrees in the mid section B, and 5 to 10 degrees in the upper section C of the spine. The curvature of any individual rod between adjacent vertebrae can be selected to match the degree of angular deformity at that location, thereby providing for much more refined treatment of scoliosis than is possible with apparatus of the prior art. Furthermore, by using an individual corrective rod for each pair of adjacent vertebrae, the force due to growth on any one screw 4 (fixation point) is only the force exerted by one growth plate, and therefore is comparatively small. If correction of a scoliosis using known apparatus which fix rods to the spine only at the top and bottom thereof were attempted, the fixation points proximally and distally rods would have to withstand the force due to growth generated by each of the growth plates, and would result in comparatively large forces on the fixation points. In the apparatus of the invention the force generated by each growth plate is harnessed locally in the construct spreading the forces on the screws 4 (the fixation elements) evenly.

In Figure 3, the vertebrae X and X" are separated by a vertebra X'. Apparatus 1 is fitted to the vertebrae X and X". Vertebra X' is fitted with an attachment (illustrated in Figure 3b) comprising a threaded shank 4a and a head in the form of an eye 5a. The rod 8 slides in the eye 5a and a corrective force is exerted on the vertebra X'.

Referring to Figure 4a, an alternative rod 10 is illustrated. As well as being cutved, the rod 10 comprises a track 11. In Figure 4b, there is shown a slide element 12. The bore 13 in which the rod

10 slides includes a channel 14 in which the track 11 slides. The track 11 has a pitch so that as the rod 10 is drawn out of the slide element 12 the rod is caused to rotate about its own axis A-A. This feature allows for the apparatus of the invention to correct rotational misalignment between adjacent vertebrae. As will be clear from Figure 4a, in order to correct for rotational misalignment, there must be no rotational movement between the rod and the slide element in which the rod is located. As an alternative to a track running along a rod of substantially circular cross-section, the rod could have a non-circular cross-section, for example square, and this could run in a slide element having a correspondingly shaped bore. The rod 10 illustrated in Figure 4a is marked at each end with indicia to tell the surgeon which way round the rod should be inserted. The arrow points towards the apex of the scolosis.

Figures 5a to 5d assist in explaining how the apparatus of the invention can be used to correct skeletal misalignments other than in the spine. Figure 5a illustrates a normal foot, where the bones of the lateral ray (see Figure 5c) lie on an axis L-L, and the bones of the medial ray (see Figure 5d) lie on an axis M-M. Figure 5b illustrates a club foot, where instead of all the bones of the lateral ray lying on the axis L-L, only the calcaneus 21 of the lateral ray lies on this axis, the cuboid 22 and metatarsal 23 lying on an axis L'-L' set at an angle Y to the axis L-L. In the case of the medial ray, instead of all the bones 24 to 27 thereof lying on the axis M-M, only the talus 24 of the medial ray lies on this axis. The navicular 25, the inner cuneiform 26 and the metatarsal 27 lie on an axis M'-M' set at an angle Z to the axis M-M. The misalignment of the lateral and medial rays of the club foot illustrated in Figure 5b can be corrected by attaching the apparatus 1 illustrated in Figures 1 to 4 to the bones 21 and 22 of the lateral ray and bones 24 and 25 of the medial ray. The radius of curvature of the rod 8 and bores 7 must be selected to match the angle of misalignment Y or Z respectively. The forefoot supination pronation profile could be corrected by a rotational component built into the rod. The rotational misalignment between the talus and calcaneus in club foot could be corrected by an arrangement of the type illustrated in Figure 4a, 4b is required. The relationship of the talus to the tibia could also be addressed.

As well as being used to correct misalignment between bones, the apparatus of the invention can also be used to correct some deformities occurring within a bone. For example, some conditions such as Perthes disease and developmental dysplasia of the hip (DDH) lead to rotation of the femur, which currently is corrected by breaking the femur, rotating one part of the broken femur relative to the other and re-joining the two parts of the bone. As part of treatment for various diseases reshaping the femur may be desirable. Instead of performing a varus derotation osteotomy the same effect could be obtained gradually using this device. As can be seen from Figure 6, the femur 30 comprises an upper part 32 which includes the ball part 33 of the ball and socket hip joint, and a lower part 31. The lower and upper parts 31, 32 are either side of a growth plate 34. The apparatus of the invention can be used to generate a torsional force on the femur, which can be used to correct a developing torsional deformity. A screw 35 is inserted into each of the lower and upper parts 31, 32 of the femur. Attached to these screws are slide elements 36, each including a bore 37 in which a curved rod slides. As the child grows, the distance between the screws 35 increases and the shaped of the rod 38 causes a torsional force to be exerted on the lower part 31 with respect to the upper part 32 of the femur, thereby causing the deformity to be corrected. This use of the apparatus of the invention is particularly useful as the outcome of an osteotomy (breaking and re-setting a bone) is not always as successful as would be desirable. Also, in cases of minor deformity, such as rotational deformities in the lower limb, the risks of a major operation may be considered too great given the level of disability. The risks associated with fitting apparatus of the invention are very low, and therefore the invention could be used to treat patients having minor deformities.

Figures 7a to 7f illustrate a locking arrangement for locking a slide element to a screw. Figure 7a illustrates a slide element 40. Extending from one end thereof is a first part of a locking element, which consists of a semi-circular portion 41 having a bore 42 located in its flat surface. Figure 7 b illustrates a second slide element 43. Extending from one end is the second part of the locking element, which consists of a semi-circular portion 44 having a protrusion 45 extending from its flat surface. The protrusion 45 is dimensions so as to mate with the bore 42. The main body 42a of the

slide element 40 may be set at an angle to the semi-circular portion 41, and likewise the main body 44a of the slide element 43 may be set at an angle to the semi-circular portion 44. A range of slide elements may be produced, the angle between the main body and the semi-circular portion that engages with the screw head 48 being different. A slide element would then be selected to match the angular displacement of the bones whose position is to be corrected.

Figures 7c and 7d illustrate a screw 46 having a threaded shaft 47 and a head 48. A pair of slide elements 40, 43 is attached to the screw 46 illustrated in Figures 7c and 7d. When the protrusion 45 of the second locking element mates with the bore 42 of the first locking element, the two elements form a circular cross-section. The screw head 48 includes a semi-circular surface 51 upon which the outer surface of the first locking element rests. The first and second locking elements 41, 44 and hence the slide elements 40 and 43 of which they form a part are held tightly in the screw head 48 by an externally threaded nut 50 which mates with an internally threaded wall 49 of the said screw head 48.

Figures 7e and 7f illustrate first and second end pieces 51 and 53 including a protrusion 52 and bore 54 respectively. The protrusion 52 of end piece 51 engages with the bore 42 of slide element 40, so that the slide element can be locked to a screw head 48 without the attachment of the slide element 43. Similarly, the protrusion 45 of the slide element 43 engages with the bore 54 of the end piece 53, so that the slide element 43 can be locked in place in a screw head.

Where the apparatus is being used to correct a torsional deformity, the screw head and the outer surfaces of the locking elements must not allow rotation therebetween. This could be achieved by making the semi-circular surfaces 42, 44 and the inner surface 55 of the screw head rectangular for instance.

Figure 8 illustrates a slide element 60 including a bore 62 in which a rod may slide. The slide element 60 has a main body 61 and an end piece 62 mounted telescopically therein. The end piece 62 includes grooves 63 which engage with protrusions 64 to define the direction in which the end piece

may move, and the extent of such movement. The end piece 62 also mounts an element 65 which locks into a screw head in a similar manner to that illustrated in Figures 7a to 7f. The apparatus is fitted to a patient such that the end-piece is fully extended. When the bones to which the apparatus is fitted are under load, for example when standing, the end piece 62 slides into the main body 61. This ensures that the bones carry load, which is important to minimise stress shielding of the bone and reduce stresses on the implant.

The apparatus of the invention may be used on adults where no growth is expected, in which case the rods are fixed, rather than slidable, with respect to the screws fixed to the bones. The apparatus would typically be used in operations to fuse together vertebrae and its purpose would be to hold the spine in the desired shape whilst the vertebrae fused together.

Whereas the apparatus described with reference to Figure 1 comprises a rod slidably mounted in adjacent slide elements, the apparatus illustrated in Figures 9a and 9b comprises a first element 100 which includes a bore 102 and a second element 101 which includes a rod 103. The rod 103 slides in the bore 102 and is attached to a block 104 which is itself attachable to a vertebrae in the same manner as illustrated in Figure 1. A threaded bore 105 is provided in wall 106 of the first element 100, the threaded bore 105 receiving a grub screw 107 that is adjustable to either permit or prevent the rod 103 sliding in the bore 102. In use the first and second elements 100, 101 are attached to fixation points provided by fixation device, such as those illustrated in Figures 1 and 2. The second element 101 is typically attached to a fixation point below the fixation point to which the first element 100 in the bore 102 of which the rod 103 slides. As the person grows, the deformity is corrected due to the angle of curvature of the rod.

Once a defined amount of growth has occurred the corrective effect of the device may be reduced or removed by providing one or both ends of the rod with a taper which permits lateral movement between the rod and the bore in which it slides.

With reference to Figures 1 and 2 and 9a an 9b, deformity correction is achieved by placing the device in under tension, that is adjacent vertebrae are brought together and the device fitted achieving as much correction as is possible at implantation, and then the residual deformity correction is achieved by 5mm of growth at that motion segment. Deformity in the coronal plane and control of extent of kyphosis or lordosis (saggittal plane) is achieved by cutting the rod and bore(s) in an arc such that 5mm movement along the circumference of the arc/circle would give the appropriate angular correction. Thus if 10 degrees correction was required with 5mm movement:

10 degrees is 1/36 of a circle

5mm is 1/36 of circumference of required circle

180mm is circumference of circle required to give 10 degrees correction with 5mm movement

 $2\Pi R = circumference = 180$

 $R = 180/2\Pi mm$

Similarly any corrective angle can be calculated for a movement of a particular distance. Rotational correction is addressed by means of a spiral in the rod and bore (see Figures 4a and 4b).

The distances between the screws after insertion and tensioning would be expected to be about 2cm in the thoracic spine and 3cm in the lumbar spine in young adolescents and correspondingly smaller in younger children. The screw diameter used in the vertebral body would be as large as possible for maximum strength and need at least 12mm of length in each rod to attach to the modular rod. (assuming 9mm screw with 3mm extra for locking mechanism) For a lordoscoliosis a few degrees of kyphosis would be desirable at each level and also a few degrees of rotation would be desirable.

With reference to Figures 1 to 3a and 9a and 9b, when correcting a deformity requiring the rod and slide element to move apart, the power of growth alone may not be sufficient in all cases to drive elongation of the implant so it may be necessary to insert a driver device in to the rod to push the two components of the device apart. This could take the form of a spring or an osmotic pressure

device inserted into the lumen/bore of the outer rod and pushing on the end of the inner rod. The driver device would provide a continuous/constant pressure helping to elongate the device as growth occurred.

The device of the invention may also be used in the correction of scoliosis in skeletally mature patients. The correction of scoliosis with modern pedicle screw, hook, rod systems is achieved by loading the spine to reduce it to the desired configuration using a combination of stress relaxation of the tissues and flexibility of the deformity to achieve correction. These instrumentation systems do not however allow accurate segmental correction, eg the rod rotation technique does not derotate the spine but rather tends to rotate it more in the direction of the deformity.

The device of the invention described for use as a growing rod can be used as a means of accurately realigning spinal segments in adult scoliosis correction. The device is designed so that when it is extended it fits on to the deformed spine between adjacent vertebral fixation points, such as pedicle screws (see Figure 9a). When the rod is compressed it shortens and realigns the segments to the desired configuration (Figure 9b). It is then locked in this configuration using the grub screw 107. The realignment of the spinal segments can be performed in the coronal, saggittal and rotational planes simultaneously using this method. The device used at a particular level will give the required saggittal profile for that segment and derotate and compress the segment so as to achieve a near anatomical spinal alignment.

The device of the invention allows the spine to be realigned much more accurately on a segmental basis with derotation at each level. Moreover the spine could always be instrumented on the convex side first where the pedicles are larger and stronger and further away from the spinal cord. Segmental correction as described could give a better cosmetic result by derotating the ribs helping reduce the size of the residual rib hump and would allow each level to be adjusted several times to gain the maximum curve reduction by better utilising the stress relaxation properties of the spine. For example, using the embodiment illustrated in Figures 9a and 9b, the deformity between adjacent

vertebrae could be corrected as far as is possible and the grub screw 107 tightened. The tissues around the vertebrae then relax permitting further correction of the deformity.

When used in the correction of deformity in skeletally mature patients the device may be made of titanium, which is the material commonly used in scoliosis implants, as the implant is used in a locked configuration and hence no bearing/movement is involved once the procedure has been completed. Also its bearing surfaces do not need to be highly polished (as they would need to be in the growing rod implant).

This implant system of the invention can be applied to the deformed spine and then gradually tensioned to slowly and systematically reduce the spinal deformity. This will make reduction of large curves easier as the difficulties with reducing the spine to the rod and the risk of implant pullout in that process will be greatly reduced. Thus the instrumented spine can be tensioned at each level and a gradual reduction achieved with avoidance of stress peaks on individual bone fixation points and more fully utilising the spine's stress relaxation properties. This technique may be of particular benefit in procedures where a vertebrectomy has been required. The implant would provide stability during the vertebrectomy and then allow a gradual controlled reduction.

Claims

Implantable apparatus for use in the correction of skeletal deformities, the apparatus comprising a rod, a pair of spaced apart attachment members, each of the attachment members being attachable to a bone, at least one attachment member mounts a rod receiving member, the rod being slidable along a predetermined path with respect to the rod receiving member.

- Implantable apparatus according to Claim 1, wherein each attachment member mounts a
 rod receiving member and the rod is mounted in the rod receiving members.
- Implantable apparatus according to Claim 2, wherein the rod is slidably mounted in each
 of the rod receiving members.
- 4. Implantable apparatus according to any preceding claim, wherein the rod is curved.
- 5. Implantable apparatus according to any preceding claim, wherein the rod and/or at least one of the rod receiving members comprise means to prevent rotation of the rod in the or each rod receiving member.
- 6. Implantable apparatus according to Claim 5, wherein the said means to prevent rotation of the rod in the or each or receiving member comprises a track mounted on the rod, and an indent in the rod receiving member in which the track slides.
- 7. Implantable apparatus according to Claim 6, wherein the track is formed in a spiral.
- Implantable apparatus according to Claim 6, wherein the rod is non-circular in crosssection and slides in a correspondingly shaped element.
- Implantable apparatus according to any preceding claim, wherein the rod includes a
 plurality of sections, one being telescopically slidable within the other.

10. Implantable apparatus according to Claim 9, wherein the ends of the rod are fixed to the rod receiving members.

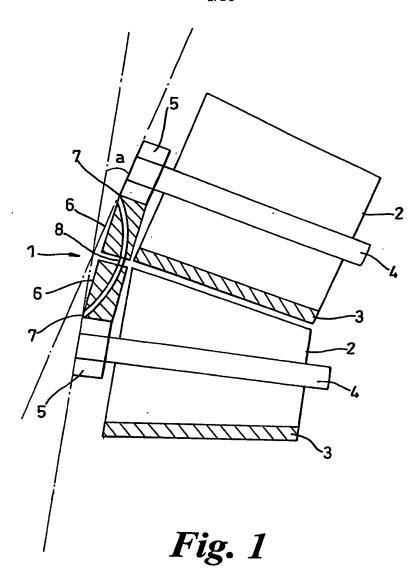
- 11. Implantable apparatus according to any preceding claim, wherein the rod sections include means to prevent rotation of one rod section relative to another.
- 12. Implantable apparatus according to Claim 11, wherein the said means to prevent rotation comprises a track projecting from one rod section, which slides in an indent in another rod section.
- 13. Implantable apparatus according to Claim 11, wherein the sections of the rod are noncircular in cross-section.
- 14. Implantable apparatus according to any preceding claim, wherein the attachment member includes a head and the rod receiving member is attached to the head.
- 15. Implantable apparatus according to any preceding claim, wherein the attachment members are selected from the group comprising: a screw, a bolt, a blade plate, a pedicle hook, and a laminar hook.
- 16. Implantable apparatus according to Claim 14 or 15, further comprising a locking means to lock a rod receiving member to an attachment member, the locking means comprising first and second lock elements, wherein the first and second lock elements engage with each other, are together locked to the attachment member by a third lock element.
- 17. Implantable apparatus according to Claim 16, wherein the attachment member includes a head shaped and dimensioned to receive co-operating first and second lock elements, and the said third lock element in the form of a plug.

18. Implantable apparatus according to Claim 16 or 17, wherein the first and second lock elements are each part of a rod receiving member.

- 19. Implantable apparatus according to Claim 18, wherein the first and second lock elements are each set at an angle to a main body of the rod receiving member.
- 20. Implantable apparatus according to any preceding claim, further comprising means to retain a rod that is slidably mounted in a rod receiving member in the said rod receiving member.
- 21. Implantable apparatus according to any preceding claim, wherein the rod is curved in two planes.
- 22. Implantable apparatus according to any preceding claim, wherein the rod comprises an indicia indicating the direction the rod should be oriented.
- 23. Implantable apparatus according to any preceding claim, further comprising a guide member attachable to a bone, the guide member comprising an opening for receiving a rod.
- 24. Implantable apparatus according to any preceding claim wherein at least one end of the rod is tapered.
- 25. Implantable apparatus according to any preceding claim, comprising a plurality of attachment members and a plurality of rods, each attachment member being attachable to a bone, and opposing ends of the rod being mounted in respective rod receiving members.
- 26. Implantable apparatus according to any preceding claim, further comprising a lock for preventing the rod from sliding with respect to the rod receiving member.

27. Implantable apparatus for use in the correction of skeletal deformities, the apparatus comprising a rod, a pair of spaced apart attachment members, each of the attachment members being attachable to a bone, wherein at least one attachment member mounts a rod receiving member, and wherein the rod is immovably connected to the rod receiving member.

- 28. Implantable apparatus according to Claim 27, comprising a plurality of attachment members, and a plurality of rods, each attachment member being attachable to a bone, and each rod being fixed to a pair of spaced apart attachment members.
- 29. A kit of parts comprising apparatus according to any preceding claim and a plurality of rods each rod having a different radius of curvature, and corresponding rod receiving members.
- 30. A method of correcting skeletal deformity in an immature patient comprising the step implanting the apparatus as claimed in any of Claims 1 to 29 into said patient.
- 31. A method of correcting skeletal deformity in an immature patient comprising the additional step of adjusting the positions of adjacent vertebrae.
- 32. A method of correcting skeletal deformity in a mature patient comprising the step of implanting the apparatus as claimed in any of Claims 1 to 29 into said patient, adjusting the positions of adjacent vertebrae and locking the apparatus.
- 33. Implantable apparatus substantially as shown in, and as described with reference to, the drawings.
- 34. A method of correcting skeletal deformity substantially as shown in and as described with reference to, the drawings.



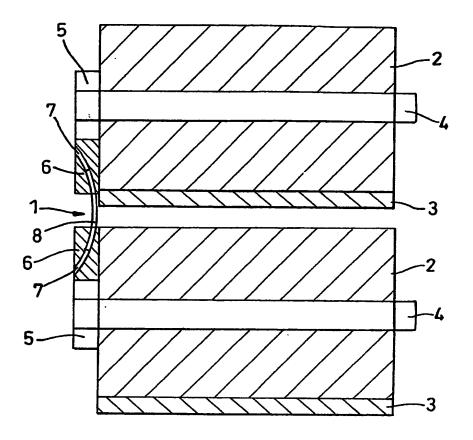
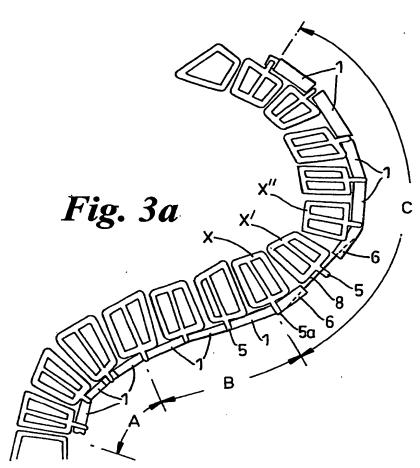


Fig. 2





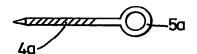
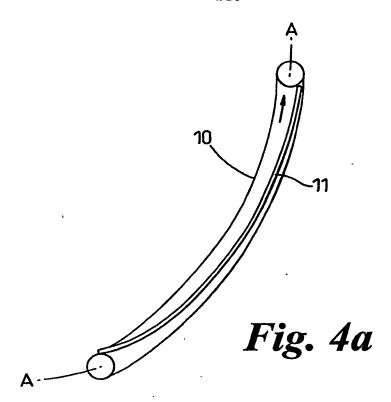


Fig. 3b





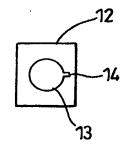
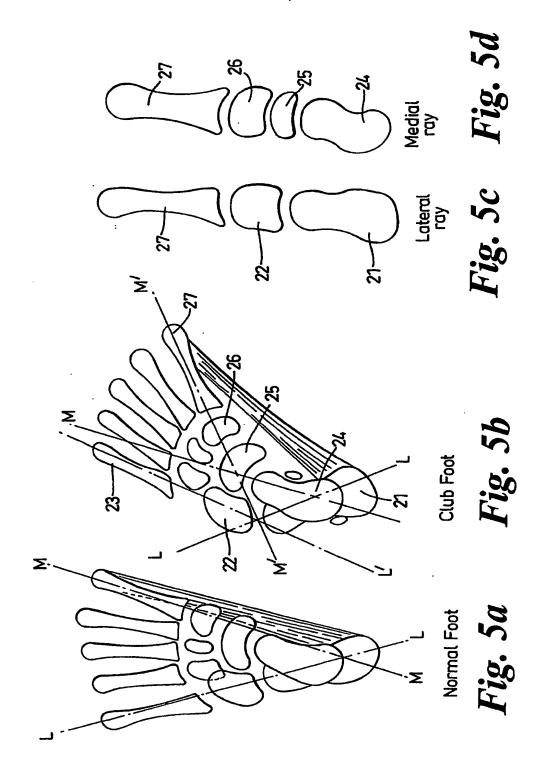


Fig. 4b



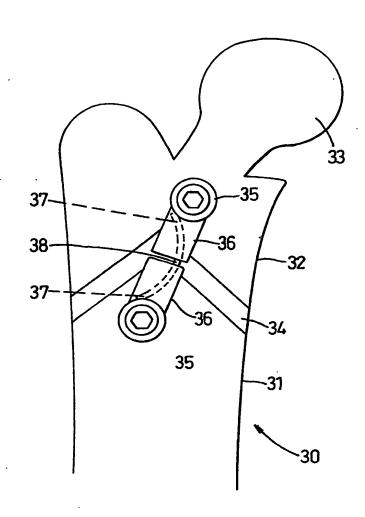
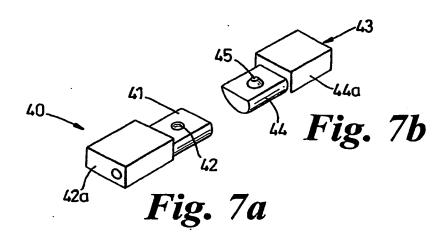
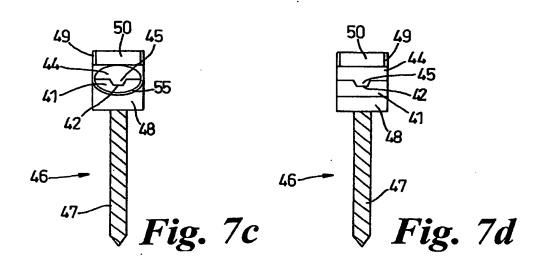
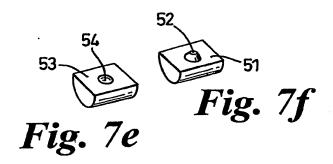


Fig. 6







8/10

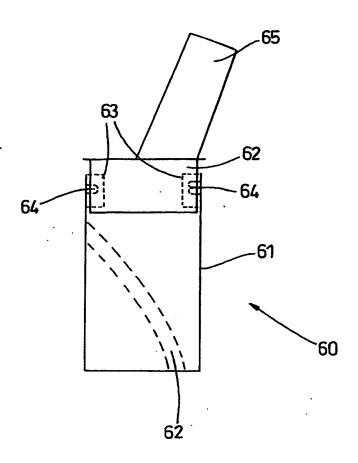


Fig. 8

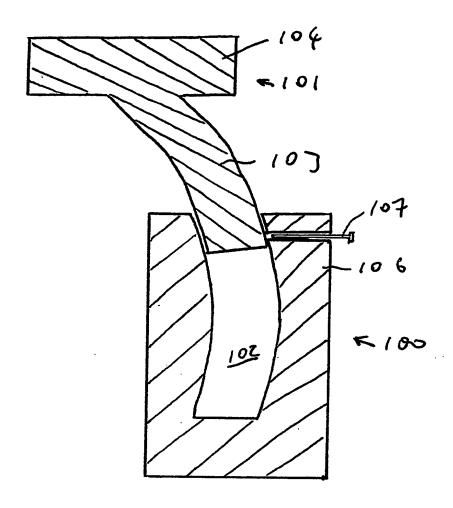


Figure 9A

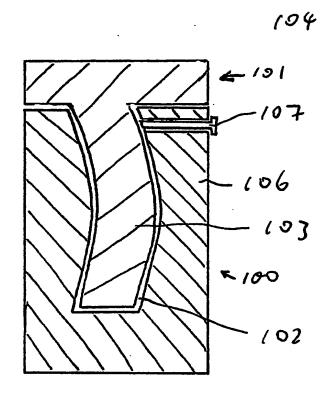


Figure 9B

Interional Application No PCT/6B2005/002210

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B17/80 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\begin{tabular}{ll} \begin{tabular}{ll} Minimum documentation searched (classification system followed by classification symbols) \\ IPC 7 & A61B \end{tabular}$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to daim No.
X	US 4 697 582 A (WILLIAM ET AL) 6 October 1987 (1987-10-06) abstract; claim 1; figures 1,3,4	1-6,8, 14-29
Y	column 1, lines 9-14 column 2, lines 57-64	9-13
X	WO 02/17803 A (HOPITAL SAINTE-JUSTINE; RIVARD, CHARLES-HILAIRE; DUJOVNE, ARIEL) 7 March 2002 (2002-03-07) abstract; figure 1 page 10, lines 14-33; claim 1	1-5, 14-29
X	FR 2 709 245 A (FAIRANT PAULETTE; MARTIN JEAN RAYMOND) 3 March 1995 (1995-03-03) abstract; figures 1-5	1-5, 14-29

Y Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
Special categories of cited documents: A' document defining the general state of the art which is not considered to be of particular relevance E' earlier document but published on or after the international filing date L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) O' document referring to an oral disclosure, use, exhibition or other means P' document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cled to understand the principle or theory underlying the invention. "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone. "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the International search report
23 August 2005	30/08/2005
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Macaire, S

2

Interpletation No PCT/GB2005/002210

C (Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	101/462003/002210	
tegory °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
(US 6 193 720 B1 (YUAN HANSEN A ET AL) 27 February 2001 (2001-02-27) abstract; claim 1; figures 1,9,12,22	1-5, 14-29	
K	WO 02/43602 A (GAINES, ROBERT, W., JR) 6 June 2002 (2002-06-06) abstract; claims 1,8	1-5, 14-29	
Y	WO 02/053038 A (MITKOVIC, MILORAD) 11 July 2002 (2002-07-11) abstract page 3, paragraph 1	9-13	

2



Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This international Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 30-34 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. X Claims Nos.: 33 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically: see FURTHER INFORMATION sheet PCT/ISA/210
See FURTHER INFORMATION SHeet FOT/ ISA/ 210
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This international Searching Authority found multiple inventions in this international application, as follows:
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the Invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 30-34

Rule 39.1(1v) PCT - Method for treatment of the human or animal body by surgery

Continuation of Box II.2

Claims Nos.: 33

In view of the wording of claim 33 presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search on claim 33 is impossible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

Intra-ional Application No PCT/GB2005/002210

						.005/ 002210
dited	atent document d in search report		Publication date		Patent family member(s)	Publication date
US	4697582	Α	06-10-1987	FR	2553993 A1	03-05-1985
				DE	3477465 D1	03-05-1989
				EP	0140790 A2	08-05-1985
				JP	60111651 A	18-06-1985
MO	0217803	Α	07-03-2002	US	6554831 B1	29-04-2003
	021,000	• • •	0, 00 2002	ΑÜ	8745501 A	13-03-2002
				WO	0217803 A2	07-03-2002
				CA	2419560 A1	07-03-2002
				EP	1313403 A2	28-05-2003
				ĴΡ	2004507313 T	11-03-2004
 FR	2709245	A	03-03-1995	FR	2709245 A1	03-03-1995
1 1	2707243	n	05 05 1995	AT	186192 T	15-11-1999
				AU	7265994 A	21-03-1995
				AU	7266094 A	21-03-1995
				AU	7266194 A	21-03-1995
				AU	7539994 A	21-03-1995
				CA	2170273 A1	
				CA		02-03-1995
				CA	2170275 A1	02-03-1995
					2170276 A1	02-03-1995
				CA	2170277 A1	02-03-1995
			•	DE	69421544 D1	09-12-1999
				EP	0773747 A1	21-05-1997
				EP	0715506 A1	12-06-1996
				EP	0715507 A1	12-06-1996
					0700000 81	04 07 1000
				EP	0722298 A1	24-07-1996
				EP WO	9505783 A1	02-03-1995
				EP WO WO	9505783 A1 9505784 A1	02-03-1995 02-03-1995
				EP WO WO WO	9505783 A1 9505784 A1 9505785 A1	02-03-1995 02-03-1995 02-03-1995
				EP WO WO WO	9505783 A1 9505784 A1 9505785 A1 9505786 A1	02-03-1995 02-03-1995 02-03-1995 02-03-1995
				EP WO WO WO FR	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995
				EP WO WO WO FR FR	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995
				EP WO WO WO FR FR FR	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995
				EP WO WO FR FR FR US	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998
				EP WO WO FR FR US	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998 31-03-1998
				EP WO WO FR FR FR US	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998
	6193720	B1	27-02-2001	EP WO WO FR FR US	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998 31-03-1998
	6193720 0243602	B1 A		EP WO WO WO FR FR US US	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A 5733284 A 5797910 A	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998 31-03-1998 25-08-1998
				EP WO WO WO FR FR US US	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A 5733284 A 5797910 A 6036693 A	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998 31-03-1998 25-08-1998
				EP WO WO WO FR FR US US	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A 5733284 A 5797910 A 6036693 A 2002068940 A1 1990902 A 1408858 A1	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998 31-03-1998 25-08-1998
				EP WO WO WO FR FR US US	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A 5733284 A 5797910 A 6036693 A	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998 31-03-1998 25-08-1998
WO			06-06-2002	EP WO WO WO FR FR US US US AU EP	9505783 A1 9505784 A1 9505785 A1 9505786 A1 2709246 A1 2709247 A1 2709248 A1 5704937 A 5733284 A 5797910 A 6036693 A 2002068940 A1 1990902 A 1408858 A1	02-03-1995 02-03-1995 02-03-1995 02-03-1995 03-03-1995 03-03-1995 03-03-1995 06-01-1998 31-03-1998 25-08-1998

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS

IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT OR DRAWING

BLURRED OR ILLEGIBLE TEXT OR DRAWING

SKEWED/SLANTED IMAGES

COLOR OR BLACK AND WHITE PHOTOGRAPHS

GRAY SCALE DOCUMENTS

LINES OR MARKS ON ORIGINAL DOCUMENT

REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

IMAGES ARE BEST AVAILABLE COPY.

☐ OTHER:

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.